UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Criminal No. 13-00273 (SRN/JJK)

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	**ORDER**
	)	
v.	)	
	)	
MORAN OZ (2);	)	
BABUBHAI PATEL (3);	)	
ELIAS KARKALAS (8);	)	
PRABHAKARA RAO TUMPATI (9);		
Defendants.		

Jacqueline Blaesi-Freed, Linda I. Marks, U.S. Department of Justice, Consumer Protection Branch, 450 5th St. NW, Ste. 6400, Washington, DC 20001, and Roger J. Gural, U.S. Department of Justice, Civil Division, P.O. Box 386, Washington, DC 20044, for the United States of America.

Joseph S. Friedberg, 701 4th Ave. S., Ste. 300, Minneapolis, MN 55415, and Robert D. Richman, P.O. Box 16643, St. Louis Park, MN 55416, for Defendant Moran Oz.

Brian N. Toder, Chestnut Cambronne, PA, 17 Washington Ave N., Ste. 300, Minneapolis, MN 55401 for Defendant Babubhai Patel.

Daniel L. Gerdts, 247 Third Ave. S., Minneapolis, MN 55415, John C. Brink, 310 4th Ave. S., Ste. 1008, Minneapolis, MN 55415, for Defendant Elias Karkalas.

James E. Ostgard, Ostgard Law Office, P.O. Box 582536, Minneapolis, MN 55458, Paul Daniel Schneck, Paul Daniel Schneck, LTD, 222 South 9th St., Ste. 1600, Minneapolis, MN 55402, for Defendant Prabhakara Rao Tumpati.

SUSAN RICHARD NELSON, United States District Judge

This matter is before the Court on Defendant Moran Oz's ("Oz") Objections to the Report and Recommendation ("Oz Objs.") [Doc. No. 474], Defendant Elias Karkalas'

("Karkalas") Objections to the Report and Recommendation ("Karkalas Objs.") [Doc. No. 475], and Defendant Prabhakara Rao Tumpati's ("Tumpati") Objections to the Report and Recommendation ("Tumpati Objs.") [Doc. No. 473]. These various objections all pertain to the Report and Recommendation ("R & R") issued by Magistrate Judge Keyes ("Judge Keyes") on February 1, 2016.[1] The United States of America ("the Government") filed timely responses to each set of objections: Government's Memorandum in Response to Defendant Oz's Objections ("Resp. to Oz") [Doc. No. 486]; Government's Memorandum in Response to Defendant Karkalas' Objections ("Resp. to Karkalas") [Doc. No. 487]; and Government's Memorandum in Response to Defendant Tumpati's Objections ("Resp. to Tumpati") [Doc. No. 485]. Defendant Babubhai Patel ("Patel") filed a Motion to Join Certain Motions of Co-Defendants [Doc. No. 417] which Judge Keyes recommended be denied. (See R & R at 11, 34.) Patel did not file any objections to the R & R. Defendant Oz's Motion to Dismiss Certain Counts as Duplicative [Doc. No. 376] and the Government's Motion to Dismiss Duplicative Counts [Doc. No. 395] were also addressed by the R & R. (See R & R at 32–34.) Neither party objected to Judge Keyes' recommended resolution of those motions.

For the reasons set forth herein, the objections of Defendants Oz, Karkalas, and Tumpati are overruled and the R & R is adopted in its entirety. Defendant Oz's Motion to Dismiss Certain Counts for Failure to State an Offense [Doc. No. 377] is denied and his Motion to Dismiss Certain Counts as Duplicative [Doc. No. 376] is denied as moot.

[1] This same R & R was docketed four times, once for each of the above-captioned defendants. (See Doc. Nos. 462, 463, 464, 465.)

Defendant Patel's Motion to Join [Doc. No. 417] is denied. Defendant Karkalas' Motion to Dismiss Certain Counts for Failure to State an Offense [Doc. No. 340], Motion to Dismiss Certain Counts as Void for Vagueness [Doc. No. 339], and Motion to Dismiss Certain Counts for Violating Due Process Rights [Doc. No. 353] are denied. Defendant Tumpati's Motion to Dismiss Certain Counts as Void for Vagueness [Doc. No. 379] and Motion to Dismiss [Doc. No. 380] are denied. The Government's Motion to Dismiss Counts 61–72 [Doc. No. 395] is granted, except that paragraphs 1 through 6 of Counts 61–72 are not dismissed so far as they are incorporated into other Counts that remain in the Indictment.

I. BACKGROUND

The extensive procedural history of this matter is well documented in the R & R and not disputed by the parties. Thus, for the sake of brevity, the Court refers to the R & R throughout this Order when discussing this undisputed history.

The Government alleges that several defendants conspired to violate the Food Drug and Cosmetics Act ("FDCA"), introduced misbranded drugs into interstate commerce, conspired to commit mail and wire fraud, committed mail and wire fraud, unlawfully distributed and dispensed controlled substances, conspired to launder money, and conspired to distribute controlled substances. (R & R at 1; Indict. [Doc. No. 5].) Relevant to the present matter, the Government charges Karkalas, Oz, and Patel with violating the Controlled Substance Act ("CSA") and its associated regulations by distributing a drug—Fioricet—through an online pharmacy called RX Limited without

the necessary prescriptions, (Indict., Counts 73–83), Oz, Patel, Karkalas and Tumpati[2] (collectively, "Defendants") with conspiring to violate the FDCA, (Indict., Count 1), and Oz, Patel, and Karkalas with actually violating the FDCA, (Indict., Counts 2–23).

Defendants now look to dismiss some or all of the charges against them for a variety of reasons. (See R & R at 2; Doc. Nos. 339, 340, 353, 377, 379, 380, 417.) The bases for Defendants' motions and objections overlap in large part and the Court addresses each category of argument below. The Court must conduct a *de novo* review of any portion of a magistrate judge's report and recommendation on a dispositive matter to which specific objections are made. 28 U.S.C. § 636(b)(1); Fed. R. Crim. P. 59(b)(3); D. Minn. L.R. 72.2(b); see United States v. Raddatz, 447 U.S. 667, 673 (1980).

II. DISCUSSION

A. Karkalas' and Oz's Motions to Dismiss Certain Counts for Failure to State an Offense, Doc. Nos. 340 and 377

Karkalas and Oz ask that the CSA-related charges be dismissed.[3] (See R & R at 2.) Karkalas and Oz specifically argue that Fioricet is not a "controlled substance" under the CSA by virtue of a Drug Enforcement Agency ("DEA") exemption regulation and

[2] As Judge Keyes noted, Tumpati challenged the mail and wire fraud charges against him on vagueness grounds as well, but failed to provide any individualized argument as to why those charges were unconstitutionally vague. (See R & R at 12, n.9.) Judge Keyes recommended denying Tumpati's motion as to these charges, (id.), and Tumpati did not object, (see Tumpati Objs.). As explained later, the Court rejects Tumpati's vagueness challenges to the FDCA charges against him; to the extent Tumpati bases his vagueness challenges to the mail and wire fraud charges on those same arguments, they fail as well.

[3] Patel's Motion to Join [Doc. No. 417] sought to join Karkalas' and Oz's motions related to these Counts. Judge Keyes recommended that Patel's motion be denied for the same reasons he recommended denying Karkalas' and Oz's motions. (See R & R at 11.) As stated above, Patel did not object to the R & R.

thus the Indictment does not state a criminal offense. (See id. at 6; Oz Objs. at 1–3; Karkalas Objs. at 2–4.) Judge Keyes disagreed and held that the regulation did not exempt Fioricet from the criminal provisions of the CSA. (See R & R at 7–11.) Thus, he found that the Indictment adequately states an offense against Karkalas and Oz and recommended that their motions be denied. (Id. at 11.) Karkalas and Oz object to this recommendation and argue that Judge Keyes' analysis was flawed. (See Oz Objs. at 1–3; Karkalas Objs. at 2–4.)

The Government alleges, in relevant part, that Karkalas and Oz violated the CSA by delivering, distributing, or dispensing Fioricet, which it claims is a controlled substance. (R & R at 3, 6; Indict., Counts 73–83.) Fioricet is a compound that contains Butalbital, a derivative of barbituric acid, and other components such as acetaminophen and caffeine. (R & R at 8, n.6, 13; Indict., Count 1 at ¶¶ 6, 10.) "Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid," is a Schedule III controlled substance. 21 U.S.C. § 812, Schedule III, Part (b)(1).

The CSA provides that "it shall be unlawful for any person knowingly or intentionally to . . . distribute, or dispense . . . a controlled substance," unless that conduct is authorized by the CSA's provisions. 21 U.S.C. § 841(a)(1). Moreover, it is "unlawful for any person to knowingly or intentionally . . . deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this subchapter." 21 U.S.C. § 841(h)(1)(A). Specific examples of conduct constituting a violation of § 841(h)(1)(A) are "writing a prescription for a controlled substance for the purpose of

delivery, distribution, or dispensation by means of the Internet in violation of section 829(e) of [Title 21]," 21 U.S.C. § 841(h)(2)(B), and "offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire," 21 U.S.C. § 841(h)(2)(D). Section 829(e) requires that controlled substances dispensed through the Internet be distributed to individuals only where there is a valid prescription, meaning a prescription "issued for a legitimate medical purpose in the usual course of professional practice by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 21 U.S.C. § 829(e)(1)–(2); see also id. § 829(e)(2)(B) (further defining an "in-person medical evaluation" as one that is "conducted with the patient in the physical presence of the practitioner").

Furthermore, one violates the CSA if he knowingly or intentionally delivers, distributes, or dispenses a controlled substance "by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by section 823(f) of [Title 21.]" 21 U.S.C. § 841(h)(2)(A). The CSA requires online pharmacies to display certain information on their websites, including:

> 1) The name and address of the pharmacy as it appears on the pharmacy's [DEA] certificate of registration.
>
> 2) The pharmacy's telephone number and email address.
>
> 3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
>
> 4) A list of States in which the pharmacy is licensed to dispense controlled substances.

> 5) A certification that the pharmacy is registered under [Part C, Subchapter I, Chapter 13, of Title 21 of the United States Code] to deliver, distribute, or dispense by means of the Internet controlled substances.
>
> 6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
>
> 7) The following statement, unless revised by the Attorney General by regulation: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.".

21 U.S.C. § 831. The Government contends that Oz, Karkalas, and Patel dispensed Fioricet through RX Limited without valid prescriptions and without RX Limited displaying the required information. (See Indict., Counts 73–83 at ¶¶ 4–6.)

The Government also alleges that Karkalas and Oz violated regulations promulgated by the DEA through their distribution of Fioricet. (See R & R at 5; Indict., Counts 73–83.) Pursuant to its administrative rulemaking authority, the DEA requires that prescriptions for controlled substances "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," and places a duty upon the "prescribing practitioner" to ensure that controlled substances are properly prescribed. 21 C.F.R. § 1306.04(a). If a practitioner issues a controlled substance prescription "not in the usual course of professional treatment," such an order "is not a prescription within the meaning and intent of . . . (21 U.S.C. § 829) and . . . the

person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." Id.

Karkalas' and Oz's objections center on another DEA regulation which they claim exempts Fioricet from treatment as a controlled substance under the CSA. (See Oz Objs. at 1–3; Karkalas Objs. at 2–4; see also R & R at 6.) The DEA, through a proper delegation of authority by the Attorney General, is empowered to "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of Subchapter I of the Controlled Substances Act. 21 U.S.C. § 811(g)(3). By virtue of this statute, the DEA enacted a regulation stating that certain "compounds, mixtures, or preparations that contain a nonnarcotic controlled substance [including Fioricet[4]] . . . have been exempted . . . from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only." 21 C.F.R. § 1308.32 (hereafter "the Exempting Regulation").

Oz and Karkalas, in seeking the protection of a regulatory exemption, have the burden of establishing that the claimed exemption is applicable. 21 U.S.C. § 885(a)(1) ("It shall not be necessary for the United States to negative any exemption or exception . .

[4] The Exempting Regulation references 21 C.F.R. § 1308.13(c), which includes "[a]ny substance which contains any quantity of a derivative of barbituric acid or any salt thereof," like Fioricet. Also referenced by the Exempting Regulation is the "Table of Exempted Prescription Products," published by the DEA's Office of Diversion Control which includes Fioricet. http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf (last visited March 11, 2016).

. and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit."); see United States v. Brown, 482 F.2d 1226, 1230 (8th Cir. 1973); United States v. Riccio, 43 F. Supp. 3d 301, 305 (S.D.N.Y. 2014). Both Oz and Karkalas argue that Judge Keyes' recommendation rests on a "flawed" understanding that the Exempting Regulation did not exempt Fioricet from criminal penalties under sections 831 and 841 of the CSA. (See Oz Objs. at 1–3[5]; Karkalas Objs. at 2–4; see also R & R at 6.) They argue that because the Exempting Regulation exempts Fioricet from 21 U.S.C. § 829—which requires a valid prescription to lawfully dispense a controlled substance through the Internet—and other portions of the CSA that carry criminal penalties, Fioricet is essentially a non-controlled substance. (See Oz Objs. at 3; Karkalas Objs. at 3–4; see also R & R at 9–10.) Notably, neither Oz nor Karkalas cite a single case supporting their understanding of the Exempting Regulation. For the reasons that follow, Oz and Karkalas have failed to meet their burden of showing the Exempting Regulation operates as they claim.

The Exempting Regulation exempts Fioricet from certain portions of the CSA "for administrative purposes only." 21 C.F.R. § 1308.32. Administrative enforcement of the

[5] Oz claims that the DEA agrees with his position that Fioricet is not a controlled substance by virtue of the Exempting Regulation. (Oz Objs. at 2 (citing Doc. No. 400, Ex. A ("DEA Bulletin") (consisting of a bulletin from the DEA Office of Diversion Control, dated March 2013, discussing the different administrative treatment of Fiorinal and Fioricet under the CSA)).) However, Oz's claim of support is vastly overstated. The DEA acknowledges that, for administrative regulatory purposes, Fiorinal and Fioricet are treated differently under the CSA with Fioricet being labelled an "exempt prescription product." (See DEA Bulletin.) However, the bulletin clearly states that "while exempted prescription products have been exempted from the application of certain regulatory provisions of the CSA . . . [s]uch products also contain a Schedule III controlled substance and are not exempt from the criminal sanctions of the CSA." (Id.)

CSA is distinct from its criminal enforcement. 21 C.F.R. § 1301.41(b) ("Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the [CSA] or any other law of the United States."); 21 U.S.C. § 847 ("Any penalty imposed for violation of this subchapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law."). Thus, by its plain language, the Exempting Regulation applies only to the administrative enforcement of certain parts of the CSA.

Further evidence of the limited scope of the Exempting Regulation is that 21 U.S.C. §§ 831 and 841—sometimes referred to as the "criminal provisions" of the CSA—are *not* included in the list of statutory sections from which Fioricet is exempted for administrative purposes. See id. Nor are 21 C.F.R. §§ 1306.04 and 1306.09 included in that exempted list. See id. The DEA plainly could have exempted Fioricet more broadly, see 21 U.S.C. § 811(g)(3) (allowing for the exemption of a compound or mixture "from the application of all or any part of" Subchapter I of the CSA), but instead chose to limit the exemption to certain statutory and regulatory provisions for administrative purposes only.[6] The non-exempted criminal provisions of the CSA, as well as the non-exempted DEA regulations, are the bases for CSA charges against Karkalas and Oz. (Indict., Counts 61–72 at ¶¶ 1–6; Indict., Counts 73–83.)

[6] Fioricet is exempted from the registration, labeling, packaging, record-keeping, and security requirements of the various statutory and regulatory provisions listed in the Exempting Regulation. See United States v. Riccio, 43 F. Supp. 3d 301, 305 (S.D.N.Y. 2014).

At least two other courts have concluded that the Exempting Regulation does not exempt Fioricet from the criminal provisions of the CSA and cannot serve as the basis for dismissing charges related to those provisions. See Riccio, 43 F. Supp. 3d at 304–06; United States v. Williams, No. CR-10-0216-HE (01), 2010 WL 4669180, at *1 (W.D. Okla. Nov. 9, 2010) aff'd, 549 F. App'x 813 (10th Cir. 2013). The similarities between those cases and the present matter are striking.

In Riccio, the defendant ("Lasher") was charged with violating 21 U.S.C. § 841 by dispensing, delivering, or distributing Fioricet without a valid prescription through an online pharmacy scheme. 43 F. Supp. 3d at 303–04. Lasher argued that the Exempting Regulation made Fioricet a non-controlled substance for the purposes of the criminal provisions of the CSA. Id. at 304. The court disagreed:

> By its own terms, [the Exempting Regulation] provides an exemption strictly limited to the registration, labeling, packaging, record-keeping and security requirements delineated in a defined list of U.S. Code provisions. By implication, any statutory provision *not* expressly listed as an exemption applies with full force against Fioricet. . . . More to the point, the statutory provision under which Lasher was charged—§ 841—is not among those from which [the Exempting Regulation] exempts Fioricet.
> . . .
> On its face, an exemption "for administrative purposes only" clearly cannot and does not encompass exemptions from the criminal laws. Whatever the precise connotation and ambit of the exemption "for administrative purposes only," the one meaning it cannot have is the one that Lasher now urges. Moreover, the statutory and regulatory framework make clear that administrative enforcement for violations of the Controlled Substantive Act is entirely separate and distinct from criminal prosecutions like this one.

Id. at 305–06 (citing to 21 C.F.R. § 1301.41 and 21 U.S.C. § 847 as evidence that administrative enforcement of the CSA is separate and distinct from criminal prosecutions). Lasher also argued that because the Exempting Regulation referenced the

prescription requirements of 21 U.S.C. § 829, the exemption went beyond just the administrative realm. Id. at 306. Again, the court disagreed, "This attempt to expand a single administrative exception into a wholesale exemption from criminal penalties fails." Id.

In Williams, the defendant ("Williams") was charged with violations of the CSA related to his distribution of Fioricet. 2010 WL 4669180 at *1. Williams argued that the distribution and conspiracy counts against him should be dismissed because Fioricet was not a controlled substance pursuant to the Exempting Regulation. The court was not convinced:

> The court agrees with the defendant that Fioricet is exempt from certain registration, labeling, packaging, record-keeping and security requirements. However, the exemption is expressly limited—"for administrative purposes only." The regulation does not exempt the product from the application of Part D—Offenses and Penalties—of Subchapter I of the CSA (sections 401–422(a) of the Act). Consequently, Fioricit [sic] cannot be distributed legally unless it is delivered "by, or pursuant to the lawful order of, a practitioner," which includes a validly licensed pharmacy. 21 U.S.C. §§ 841(a); 802(10), (11), (21).
>
> The Attorney General/DEA could have exempted Fioricet "from the application of all" of subchapter I of the CSA but did not. Fioricet remains a controlled substance despite being an exempted prescription product.

Id.

This Court finds Riccio, Williams, and the plain language of the Exempting Regulation to be persuasive evidence that Fioricet is not exempt from the criminal provisions of the CSA. Oz and Karkalas have failed to meet their burden to prove that the Exempting Regulation applies as they claim. Thus, Oz's and Karkalas' motions to dismiss are denied.

B. Vagueness Objections

Oz, Karkalas, and Tumpati all claim that some of the charges against them should be dismissed because they are unconstitutionally vague. (See Oz Objs. at 3–4; Karkalas Objs. at 4–5; Tumpati Objs. at 4–6.) "The Fifth Amendment provides that '[n]o person shall . . . be deprived of life, liberty, or property, without due process of law.'" Johnson v. United States, ___ U.S. ___, 135 S. Ct. 2551, 2557 (2015). "[T]he government violates this guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." Johnson, 135 S. Ct. at 2557; see Grayned v. City of Rockford, 408 U.S. 104, 108 (1972) ("[W]e insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly."). Claims of unconstitutional vagueness not involving the First Amendment are examined under the circumstances of the case at hand. See United States v. Washam, 312 F.3d 926, 929 (8th Cir. 2002). A two-part test is employed to assess vagueness: "[f]irst, the statute must provide adequate notice of the proscribed conduct," and "[s]econd, the statute must not lend itself to arbitrary enforcement." Washam, 312 F.3d at 929.

The Court addresses each party's claims and objections related to vagueness below.

1. Vagueness and the CSA charges

Oz and Karkalas both argue that the CSA charges against them are void for vagueness. (See Oz Objs. at 3; Karkalas Objs. at 4–5; R & R at 13–14, 17, n.12.)

Specifically, they contend that a person of ordinary intelligence would not know what conduct related to the distribution of Fioricet was prohibited under the CSA because of the alleged confusion generated by the Exempting Regulation. (See Oz Objs. at 3–4[7]; Karkalas Objs. at 4; see also R & R at 17, n.2.) Judge Keyes was unpersuaded and found that the plain language of the Exempting Regulation made clear that it would not shield an individual from criminal prosecution for unlawfully dispensing or distributing Fioricet. (See R & R at 13–17.) The Court agrees with Judge Keyes' thorough analysis of Oz's and Karkalas' vagueness claims. Those claims fail for at least three reasons.

First, the Exempting Regulation plainly states that Fioricet is exempted from certain statutory and regulatory provisions of the CSA "for administrative purposes only." See 21 C.F.R. § 1308.32. The criminal provisions of the CSA which serve as the basis for the charges against Oz and Karkalas are not included in the list of administratively exempted provisions. See id. A person of ordinary intelligence would

[7] Oz claims that the Exempting Regulation even created considerable confusion within the DEA and other law enforcement agencies. (See Oz Objs. at 3–4 (citing to Doc. No. 436, Ex. 1 ("DEA Ltr.") (consisting of a legal opinion letter from the DEA's associate chief counsel, dated 3/26/2010, regarding the effect of the Exempting Regulation on criminal prosecution of those distributing Fioricet).) The DEA acknowledged, in 2010, that criminal prosecution of exempted prescription products, such as Fioricet, was "far from settled" because no such prosecution had occurred. (DEA Ltr. at 4.) It also stated that the Exempting Regulation was "likely to cause some confusion" in such criminal prosecutions. (Id.) However, Oz considerably overstates what, if any, confusion existed. The DEA noted that the Exempting Regulation was "for administrative purposes only," which "indicates unequivocally that distributors of Fioricet are subject to criminal liability unless such liability arises from a purely administrative requirement." (Id.) Further discrediting Oz's contention of law enforcement confusion is the fact that since the DEA Letter was authored, at least two successful criminal prosecutions of Fioricet distribution under the CSA have occurred. See Riccio, 43 F. Supp. 3d 301; Williams, 2010 WL 466918.

read the Exempting Provision and understand that it did not exempt the distribution or dispensing of Fioricet from the criminal provisions of the CSA. Moreover, given Karkalas' position as a well-educated physician and Oz's position as the operations manager of a large online pharmacy (see Indict., Introduction at ¶¶ 3–4, 6, 12), it is reasonable to assume they would not only inform themselves of the laws relevant to the highly regulated industry in which they worked, but be capable of understanding the plain language of those statutes and regulations. See Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498 (1982) ("The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment. Thus, economic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action."); Riccio, 43 F. Supp. 3d at 307 (finding that the defendant's status as a "highly trained pharmacist" operating in the heavily regulated online pharmacy industry weighed against the defendant's vagueness claim regarding the Exempting Regulation). Even setting aside their training, education, and industry of practice, Oz and Karkalas are presumed to be aware of criminal laws. United States v. Ray, 411 F.3d 900, 904 (8th Cir. 2005) ("[P]eople are generally presumed to be aware of the criminal laws.").

Second, "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." Vill. of Hoffman Estates, 455 U.S. at 499. The CSA contains specific intent elements. See 21

U.S.C. § 841(h); Riccio, 43 F. Supp. 3d at 307 (holding that the CSA's scienter requirement weighed against the defendant's claim of vagueness related to the Exempting Regulation and the CSA); United States v. Williams, No. CR-10-216-HE, 2011 WL 4104654, at *4 (W.D. Okla. Sept. 14, 2011) ("The specific intent requirement for the [charges alleging unlawful distribution of Fioricet] saves the statutes from potential unconstitutionality.") The Indictment charges Oz and Karkalas with "knowingly and intentionally" committing violations of the CSA. (Indict., Counts 73–83 at ¶ 6.)

Third, even if the Exempting Regulation made the potential criminality of distributing Fioricet vague—which it did not— the existence of Williams alleviated any vagueness. See United States v. Lanier, 520 U.S. 259, 266 (1997) (noting that vagueness about the scope of a criminal statute may be remedied through subsequent judicial clarification). Since at least November 2010[8] there has been a clear judicial ruling that the Exempting Regulation did not exempt Fioricet from the criminal provisions of the CSA. See Williams, 2010 WL 4669180 at *1. That ruling was subsequently approved and expounded upon by another court. See Riccio, 43 F. Supp. 3d at 304–06. Neither Karkalas nor Oz mentions Williams or Riccio in their objections or attempts to distinguish those cases from the present matter. (See Oz Objs.; Karkalas Objs.)

The Exempting Regulation did not make the potential criminality of distributing Fioricet under the CSA unconstitutionally vague. Even if it did, the specific intent

[8] Many of the specific examples of Oz's and Karkalas' alleged violations of the CSA occurred after this date. (See Indict., Counts 73–83 at ¶ 6.)

elements of the CSA and the existence of Williams alleviate any vagueness concerns. Oz's and Karkalas' motion to dismiss the CSA-related charges against them are denied.

2. Vagueness and the FDCA charges

Karkalas and Tumpati argue that the FDCA charges alleging misbranding of drugs, (Indict., Counts 1–23[9]), should be dismissed because an ordinary person would not have foreseen that issuing a prescription could constitute misbranding the drug prescribed. (See R & R at 18.) Judge Keyes disagreed and recommended denying these motions. (See R & R at 18–23.) Judge Keyes found that the FDCA "plainly requires certain potentially harmful drugs to be dispensed to patients only under the supervision of a licensed practitioner and only where that practitioner provides a prescription for such a drug." (R & R at 19.) Judge Keyes then noted that the FDCA requires a bona fide physician-patient relationship to exist for a prescription to be considered valid; without a valid prescription, the FDCA considers introduction or delivery of a drug to be misbranding. (Id. at 19–20.) Based on these findings, he concluded that "the misbranding statutes [of the FDCA] provide a 'person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly.'" (Id. at 20 (quoting Washam, 312 F.3d at 929).)

Karkalas objects to Judge Keyes' recommendation and raises a new basis for his vagueness claim—that Fioricet does not require *any* prescription by virtue of the Exempting Regulations and thus prescribing it without the necessary bona fide physician-

[9] Tumpati is charged with conspiracy to violate the FDCA while Karkalas is charged with both conspiracy and actual violation of that statute.

patient relationship could not be considered misbranding.[10] (See Karkalas Obj. at 4–5.) Tumpati generally objects that persons of common intelligence would not know that prescribing Fioricet without a valid prescription constituted misbranding under the FDCA.[11] (See Tumpati Objs. at 4–6.)

The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug, . . . that is adulterated or misbranded." 21 U.S.C. § 331(a);

[10] The Court notes that Karkalas did not raise this argument in his Memorandum of Law in support of his Motion to Dismiss [Doc. No. 437]. There is no indication that Karkalas ever presented the argument that the Exempting Regulation is a source of vagueness related to the FDCA charges to Judge Keyes. (See R & R at 18–23 (making no mention of such an argument, or the Exempting Regulation).) When presenting arguments to the magistrate judge, a party must put forth "not only their 'best shot' but all of their shots." Ridenour v. Boehringer Ingelheim Pharm., Inc., 679 F.3d 1062, 1067 (8th Cir. 2012) (quotations and citations omitted). "A party cannot, in his objections to an R & R, raise arguments that were not clearly presented to the magistrate judge." Hammann v. 1-800 Ideas.com, Inc., 455 F. Supp. 2d 942, 947–48 (D. Minn. 2006). New claims or arguments, presented for the first time in the objections to an R & R, will not be reviewed. See Britton v. Astrue, 622 F. Supp. 2d 771, 776 (D. Minn. 2008). However, in the interest of completeness, and because it does not change the Court's ruling, the Court addresses Karkalas' newly raised argument.

[11] In support, Tumpati cites United States v. Carlisle, 234 F.2d 196 (5th Cir. 1956) and claims that "federal judges, trained in the legal system and assessing laws" have concluded that the misbranding statutes are "awkward," implying they may be confusing or vague. (Tumpati Objs. at 6.) Tumpati misstates Carlisle, which in fact directly contradicts his position. There, the government appealed an order dismissing its FDCA misbranding charges against the defendant. Carlisle, 234 F.2d at 197. The Fifth Circuit Court of Appeals—trying to give "the fullest effect possible" to the defendant's argument that the FDCA's misbranding provisions were vague—described his position as claiming "that it is an unduly awkward way to go about charging an offense to have to rely upon three separated sections to make [] out [the misbranding charge]." Id. at 198–99. However, the Fifth Circuit rejected the defendant's vagueness argument and found that the indictment's recitation of the FDCA's misbranding provisions "taken together [] provided as clearly as though it had all been written out in the same section, that one dispensing [a controlled drug] contrary to the provisions of Sec. 353(b)(1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding." Id. at 199. The district court's dismissal of the misbranding charges was reversed. Id.

see also 21 U.S.C. § 333(a) (providing criminal penalties for violation of § 331(a)). The statute goes on to define "misbranded" in the following relevant way:

> (1) A drug intended for use by man which—
>
> > (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
> >
> > (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;
>
> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. *The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.*

21 U.S.C. § 353(b)(1) (emphasis added).

A valid prescription is one issued in the usual course of professional practice and for a legitimate medical purpose. See United States v. Smith, 573 F.3d 639, 652 (8th Cir. 2009). Furthermore, a valid prescription requires that a bona fide physician-patient relationship exist. Smith, 573 F.3d at 650–53 (discussing the requirements of 21 U.S.C. §§ 331(a) and 353(b)(1) related to prescriptions). Thus, if a physician issues a prescription for a drug without a bona fide physician-patient relationship, he violates 21 U.S.C. §§ 331(a) and 353(b)(1). See id.

There is nothing vague about the FDCA's misbranding provisions. See United States v. Forester, 346 F.2d 685, 686 (4th Cir. 1965) (per curium) (finding no err in the district court's rejection of the defendant's claim that the FDCA's misbranding and prescription provisions were vague); United States v. Travia, 180 F. Supp. 2d 115, 121–22 (D.D.C. 2001) (rejecting defendants' claims that FDCA misbranding and prescription provisions were unconstitutionally vague); United States v. Carlson, No. 12-cr-305 (DSD/LIB), 2013 WL 5125434, at *11 (D. Minn. Sept. 12, 2013) aff'd, 810 F.3d 544 (8th Cir. 2016) (rejecting a defendant's claim that numerous provisions of the FDCA were unconstitutionally vague); Williams, 2011 WL 4093884, at *5 ("Because the FDCA provided ample notice to [the defendant] of the conduct that was proscribed [related to misbranding], defendant's as-applied vagueness challenge fails."). A person of ordinary intelligence would understand that issuing an invalid prescription—i.e., one written without the necessary bona fide physician-patient relationship, not in the usual course of practice, or not for a legitimate medical purpose—or conspiring to do the same, constitutes misbranding under 21 U.S.C. §§ 331(a) and 353(b)(1).[12] This is precisely the charge brought against Karkalas and Tumpati. (See Indict., Counts 1–23.)

The Exempting Regulation does nothing to confuse the plain language of the FDCA. Again, the Exempting Regulation explicitly states that it is for "administrative

[12] Even if this were not true, the Indictment charges Tumpati and Karkalas with intentionally engaging in the misbranding conduct. (See Indict., Count 1 at ¶ 10.) The FDCA contains similar fraudulent intent language in its criminal penalties section. 21 U.S.C. § 333(a)(2). As previously described, a scienter element mitigates vagueness concerns. See supra Part II.B.1.

purposes only." 21 C.F.R. § 1308.32. It does not apply to any criminal statutory provision or regulation. See supra Part II.A. Furthermore, it makes no mention whatsoever of the FDCA, applying instead to certain provisions of the CSA. See 21 C.F.R. § 1308.32. It is inconceivable that a person of ordinary intelligence, let alone highly educated physicians like Karkalas and Tumpati, would think the Exempting Regulation pertained to the FDCA. Moreover, Karkalas' claim that dispensing Fioricet does not require a prescription at all because of the Exempting Regulation, (see Karkalas Objs. at 5), is meritless.[13] If Karkalas' contention were true, it is difficult to understand why he issued prescriptions for Fioricet, was allegedly paid millions of dollars to do so, and why many consumers went online looking for means to obtain such prescriptions. (See Resp. to Karkalas at 7–8 (noting this logical inconsistency and citing the Physician's Desk Reference and Final Rule for Exempted Prescription Products, both of which state that Fioricet requires a prescription).)

Tumpati's vagueness objections also fail. First, Tumpati claims that Judge Keyes erroneously relied on Riccio in rejecting his vagueness claims. (See Tumpati Objs. at 4–6.) Tumpati's claim is factually incorrect—the R & R makes no mention of Riccio when addressing Tumpati's allegation that the FDCA is unconstitutionally vague. (See R & R at 18–23.)

Second, Tumpati contends that because he is a physician and not a pharmacist like the defendant in Riccio, that case is inapplicable. (See Tumpati Objs. at 4–6.)

[13] Oz similarly claims that no prescription is required to dispense Fioricet under the CSA, 21 U.S.C. § 829, by virtue of the Exempting Regulation. (See Oz. Objs. at 3.) The Court rejects this claim for the same reasons that follow and those set forth in Part II.A.

Specifically, Tumpati claims that as a physician he could "be expected to know how to evaluate and medically treat people," but not to know the "ins-and-outs of the highly regulated prescription industry" like the pharmacist defendant in Riccio. (See id. at 5.) Tumpati's physician-pharmacist distinction is one without a meaningful legal difference. As described above, a person of ordinary intelligence, not trained as either a physician or a pharmacist, would understand that issuing an invalid prescription constituted misbranding under the FDCA. Numerous other courts have reached a similar conclusion and found no vagueness in the FDCA.

Furthermore, Tumpati's suggestion that a physician cannot be expected to know that he/she must issue valid prescriptions, else risk violating the FDCA, strains reason. As a physician issuing prescriptions to customers of an online pharmacy, Tumpati was involved with two highly regulated fields—the online pharmacy industry and the medical profession. He could thus be expected to know the statutes and regulations that applied to both, including the FDCA's misbranding provisions. See Vill. of Hoffman Estates, 455 U.S. at 498; Papachristou v. City of Jacksonville, 405 U.S. 156, 162 (1972) ("In the field of regulatory statutes governing business activities, where the acts limited are in a narrow category, greater leeway [in assessing whether a statute gives the constitutionally necessary notice of offending conduct] is allowed."); see also United States v. Dimitrov, 546 F.3d 409, 414 (7th Cir. 2008) (finding defendant operating in the highly regulated money transmission industry could be expected to know the relevant licensing requirements). The Court agrees with the Government's observation that "[o]nly a willfully ignorant medical practitioner could profess that he or she were unaware that

writing invalid prescriptions could expose them to criminal penalties under [the FDCA]." (Resp. to Tumpati at 5.)

The FDCA's misbranding provisions are not unconstitutionally vague. Karkalas' and Tumpati's motions to dismiss are denied.

C. Tumpati's Motion to Dismiss, Doc. No. 380

Tumpati argues that the Indictment is insufficient in that it did not contain "the element of the absence of a bona fide doctor-patient relationship" because Tumpati argues that he had the necessary doctor-patient relationships. (See Tumpati Objs. at 1–4.) The Government disagrees that the necessary relationships existed. (See Indict., Count 1 at ¶¶ 9–10; Resp. to Tumpati at 6–7.) However, the Court need not resolve this factual dispute since such disputes are generally issues for the jury. See Smith, 573 F.3d at 650–53 (upholding the jury instructions employed by the district court regarding the legal standard for determining if there was a valid prescription in a FDCA misbranding case). The fact that the Indictment lays out the elements of misbranding and valid prescriptions as described in 21 U.S.C. §§ 331(a), 353(b)(1), and Smith, (Indict., Count 1 at ¶¶ 7–10), is enough to put Tumpati on notice of the charges he must defend against. See Hamling v. United States, 418 U.S. 87, 117 (1974) ("It is generally sufficient that an indictment set forth the offense in the words of the statute itself, as long as those words of themselves fully, directly, and expressly, without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offence [sic] intended to be punished." (quotations omitted)); Riccio, 43 F. Supp. 3d at 308 (denying defendant's motion to dismiss misbranding charges under the FDCA where the indictment alleged that prescriptions

were issued outside a bona fide physician-patient relationship). Tumpati's motion to dismiss on these bases is denied.

D. Karkalas' Motion to Dismiss for Violating Due Process, Doc. No. 353

Karkalas claims that allowing the CSA-related charges against him to go forward is a violation of his rights under the Due Process Clause of the Fifth Amendment. (See R & R at 26; Karkalas Objs. at 5–6.) Specifically, Karkalas alleges that he detrimentally relied on the misleading advice of government actors when he concluded that Fioricet was not a controlled substance within the meaning of the CSA.[14] (See R & R at 26.) Judge Keyes, after holding an evidentiary hearing on that issue, found that none of the allegedly misleading statements amounted to a valid defense of entrapment by estoppel. (Id. at 26–32.) In particular, Judge Keyes found that the inclusion of Fioricet in the Exempting Regulation and related Exempt Prescription Products List did not "amount to a statement by a government official that Karkalas' conduct was lawful and upon which [Karkalas] could reasonably rely." (Id. at 32.) Karkalas objects, claiming that Fioricet's inclusion on the Exempt Prescription Products List "is an affirmative statement, which if not accurate, is affirmatively misleading." (Karkalas Objs. at 5–6.)

"To successfully present a defense of entrapment by estoppel, [the defendant] bears the burden of proof to demonstrate that: (1) his reliance on the government's statement was reasonable, and (2) the statement misled him into believing his conduct was legal." United States v. Benning, 248 F.3d 772, 775 (8th Cir. 2001). Only when a

[14] Alleging government officials mislead a defendant into criminal conduct is often referred to as the defense of entrapment by estoppel. See United States v. Benning, 248 F.3d 772, 775 (8th Cir. 2001)

government official affirmatively "assures a defendant that certain conduct is legal," and the defendant reasonably relies on that advice, is there a valid defense of entrapment by estoppel. Id.

Karkalas' claim of entrapment by estoppel fails for at least two reasons. First, the Exempting Regulation is not an affirmatively misleading statement. It does not state that Fioricet is exempt from the criminal provisions of the CSA.[15] On the contrary, the Exempting Regulation makes clear it is for administrative purposes only, meaning it has no application to the criminal enforcement of the CSA. The criminal provisions of the CSA Karkalas allegedly violated are not listed in the Exempting Regulation. Even if the Exempting Regulation were an incomplete explanation of the law—which it is not—that is not the sort of affirmative misrepresentation necessary for entrapment by estoppel. See United States v. Ray, 411 F.3d 900, 904 (8th Cir. 2005) ("[A]n incomplete explanation of law cannot support an estoppel-by-entrapment defense. The reason is that . . . it is not the law that a person is presumed to know what is illegal based only on what the government tells him. Rather, people are generally presumed to be aware of the criminal laws. For [a defendant] to have a viable defense of entrapment by estoppel, then, there must have been an affirmative misrepresentation." (quotations and citations omitted)); Benning, 248 F.3d

[15] The existence of the Exempt Prescription Products List does nothing to change this analysis. That List includes Fioricet, describes its component parties (including the controlled substance Butalbital), and provides other generic information about the drug. It makes no reference to any statute or regulation, nor does it purport to explain what the drugs contained therein are exempted from—thus, it cannot be the sort of affirmatively misleading statement necessary for entrapment by estoppel. Moreover, a reasonable person would not rely on the mere existence of a list entitled "Exempt Prescription Products List" to conclude that the criminal provisions of the CSA did not apply to the drugs contained on that list.

at 776 (holding that a defendant failed to establish an entrapment by estoppel defense because "[a]t most, [the defendant] suffered from a lack of explanation rather than an affirmative misleading interpretation of the statute").

Second, any reasonable person, and certainly a highly educated physician like Karkalas, would not rely on the Exempting Regulation to conclude that Fioricet was exempted from the criminal provisions of the CSA. If Karkalas were confused or uncertain about the Exempting Regulation's impact on the potential criminality of prescribing Fioricet, he should have investigated the issue further. See Benning, 248 F.3d at 776 (finding that a felon, who claimed he was misled about his ability to possess a firearm based on the wording of a federal form, should have investigated the allegedly confusing language more thoroughly before obtaining a firearm).

III. ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED THAT**:

1. Defendant Moran Oz's ("Oz") Objections to the Report and Recommendation [Doc. No. 474], Defendant Elias Karkalas' ("Karkalas") Objections to the Report and Recommendation [Doc. No. 475], and Defendant Prabhakara Rao Tumpati's ("Tumpati") Objection to the Report and Recommendation [Doc. No. 473] are **OVERRULED**.

2. The Report and Recommendation issued by Magistrate Judge Keyes on February 1, 2016 [Doc. Nos. 462, 463, 464, 465] is **ADOPTED** in its entirety.

3. Defendant Oz's Motion to Dismiss Certain Counts for Failure to State an Offense [Doc. No. 377] is **DENIED**.

4. Defendant Oz's Motion to Dismiss Certain Counts as Duplicative [Doc. No. 376] is **DENIED AS MOOT**.

5. Defendant Patel's Motion to Join [Doc. No. 417] is **DENIED**.

6. Defendant Karkalas' Motion to Dismiss Certain Counts for Failure to State an Offense [Doc. No. 340], Motion to Dismiss Certain Counts as Void for Vagueness [Doc. No. 339], and Motion to Dismiss Certain Counts for Violating Due Process Rights [Doc. No. 353] are **DENIED**.

7. Defendant Tumpati's Motion to Dismiss Certain Counts as Void for Vagueness [Doc. No. 379] and Motion to Dismiss [Doc. No. 380] are **DENIED**.

8. The Government's Motion to Dismiss Counts 61–72 [Doc. No. 395] is **GRANTED IN PART** as follows:

    a. Counts 61–72 of the Indictment [Doc. No. 5] are **DISMISSED** except that paragraphs 1 through 6 of Counts 61–72 are not dismissed so far as they are incorporated into other Counts that remain in the Indictment.

Dated: March 28, 2016

s/ Susan Richard Nelson
SUSAN RICHARD NELSON
United States District Judge